

C' than the first elevated temperature and a second pressure less than the first elevated pressure (for a time sufficient to shrink the formed balloon to a second diameter less than the first diameter.)

C<sup>2</sup> 47. (Once Amended) A method as in claim [33] 46 wherein the catheter is inserted into the gastrointestinal tract, and withdrawn therefrom, through an endoscope.

### REMARKS

Claims 11-17 and 35-47 are currently pending in the present application.

Affirmation of the provisional election made on January 7, 1998 was made by the Applicant in the Amendment filed January 9, 1998.

In the Official Action mailed February 2, 1998, the Declaration was seen as defective, the disclosure was objected to and claim 47 was rejected under 35 U.S.C. §112. Additionally, claim 11 was rejected under 35 U.S.C. 102(e) and claims 12-17 and 35-47 were rejected under 35 U.S.C. §103(a). These issues are discussed in detail below.

### *Objection to Declaration*

It has been asserted that Applicant's Declaration is defective because the application number and filing date of one of the claimed priority applications, namely, U.S. Application No. 08/392,837, is incorrect.

A new Declaration is enclosed correcting the error. Also enclosed, please find copies of a Grant of Petition and supporting documents due to an Omitted Inventor.

### *Objection to Specification*

The disclosure was objected to because of certain informalities. In response, the Applicant has amended the Specification.

***Rejection under §102***

Claim 11 was rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,500,180 to Anderson et al. (hereinafter "Anderson"). It is asserted that Anderson discloses a thermoplastic polymer material balloon, where the thermoplastic polymer material is a block copolymer material.

Applicant respectfully traverses the rejection. Anderson does not disclose or teach each and every element as set forth in claim 11, as amended, of the present application. In claim 11, an annealing process which includes heating the balloon material twice at different elevated temperatures and different pressures, wherein the second temperature and pressure are less than the first temperature and pressure. This process results in a shrinking of the balloon's diameter. The balloons prepared utilizing the shrinking step have extended, very high compliance profiles, in addition to high wall strength. The shrinking step causes the compliance curve to start from a lower point so that overall the balloon is much more compliant. In this manner the comparatively high strength of the block copolymer material is made accessible to medical device applications where high compliance is also desirable. The presently claimed invention provides unique combinations of balloon diameter, high burst strength and high compliance characteristics and also provides excellent rewrap characteristics, in comparison to high strength balloons formed by other processes. With the shrinking step, the force required to withdraw the balloon catheter from the body is low, especially for catheters designed to pass through endoscopes. The entire process and result is unique to the present invention and is not anticipated by the Anderson patent.

The shrinking process used in the invention is quite different from the heat set technique used in Anderson, in that the process of Anderson, after formation of the balloon, heats the balloon under pressure of 100-500 psi to a temperature above the blowing temperature specifically for the purpose of stabilizing/crystallizing the balloon **against shrinkage upon cooling**. The present invention is directed to exploitation of shrinkage behavior in order to increase and extend the compliance of the resulting balloon. The entire Anderson patent teaches

the heat step at an increased second temperature, relative to the initial blowing temperature. Examples of this specific teaching are shown in the patent at Column 9, lines 53-61, Column 10, lines 10-15 and in Example 1. This heat step throughout Anderson teaches in the opposite direction as that of the present application and claim 11, as amended, which requires a lower second temperature and pressure relative to the initial blowing temperature and pressure. Still further, the intended purpose of the shrinking step versus the heat step of Anderson are different. As mentioned above, the shrinking step shrinks the diameter of balloon to create an extended, high compliance profile, in addition to high wall strength, as well as the other above mentioned characteristics, and the heat step of Anderson is utilized in crystallizing the balloon to stabilize it **against shrinkage upon cooling**. As such, the above amended claim 11 is clearly distinct and not anticipated by Anderson.

***Claim Rejections -35 U.S.C. § 103***

The Examiner objects to claims 12-17, 35-42, 44 and 45 as being obvious under 35 U.S.C. §103(a) in view of U.S. Patent No. 5,500,180 to Anderson et al. (hereinafter "Anderson"). It is asserted that Anderson discloses the invention substantially as claimed, but does not disclose the specific variations of inflation pressure and diameter as claimed by the Applicant. It is further asserted that these variations would be an obvious design choice by varying and controlling the specifications in the process of making the balloons.

As discussed above in the response to the §102 rejection, Anderson does not disclose the invention substantially as claimed (claim 11), primarily because of the disparagement between the shrinking step of amended claim 11 and the heating step of Anderson. As a result and due to their dependency, claims 12-17 are similarly not made obvious because Anderson does not disclose the invention substantially as claimed, which is an important basis to the rejection in question, and as such the rejection fails.

Claims 12-17, which are dependent on claim 11, and claims 35-42, 44 and 45 are still further not obvious for the basic and resulting difference between the shrinking step of the

present invention and the heating step of Anderson. The balloons prepared utilizing the shrinking step have extended and very high compliance profiles, in addition to high wall strength. The shrinking step causes the compliance curve to start from a lower point so that overall the balloon is much more compliant. In this manner the comparatively high strength of the block copolymer material is made accessible to medical device applications where high compliance is also desirable. A balloon made using the method and materials of the present invention exhibit certain characteristics due to those materials and shrinking method. These characteristics are exemplified in claims 12-17, 35-42, 44 and 45, by claiming how the balloon performs under certain pressure. These characteristics at each point in time, or pressure, define the extended, high compliance curve, which is the result of the materials used and the shrinking method employed. As discussed above, Anderson teaches a distinctly different method of making balloons than that of the presently claimed invention and discloses distinct reasons for the differences in the methods. The present invention seeks to shrink the balloon, for the above-mentioned reasons, and Anderson teaches a heat step to stabilize/crystallize the balloon to **guard against shrinkage upon cooling**. The resulting characteristics defined in the claims under rejection are a result of the method of the presently claimed invention and are not taught by Anderson. They are not disclosed because the resulting balloons made by the method of Anderson have distinct and different characteristics due to the above discussed differences in the methods of making balloons, most notably the differences between the shrinking step of the present invention and the heat step of Anderson. Therefore, it is not suggested or obvious in light of Anderson that the balloon characteristics at certain pressures claimed in the rejected claims, which define the improved compliance curve of balloons made by the method of the presently claimed invention, would be obtained from Anderson even with simple variations of the specifications in the process of making the balloon without the distinctive shrinking methodology of the present invention.

The present invention is directed to exploitation of shrinkage behavior in order to increase and extend the compliance of the resulting balloon, the characteristics of which are

claimed by the subject claims. Burst strength is not substantially affected by the shrinking step. However the shrinking step causes the compliance curve to start from a lower point so that overall the balloon is much more compliant. In this manner the comparatively high strength of the block copolymer material is made accessible to medical device applications where high compliance is also desirable. The claimed method is clearly distinct from the methods of Anderson, resulting in balloons having differing characteristics, such that the claimed resulting characteristics of the balloons as defined in claims 12-17, 35-42 and 44-45 would not be obvious over Anderson by merely varying and controlling the specifications in the process of making the balloon, absent the benefit of Applicant's disclosure. Therefore, Applicant respectfully submits that the objection has been overcome and requests that the rejection be withdrawn.

Claim 43 was rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,500,180 to Anderson et al. (hereinafter "Anderson") in view of U.S. Patent No. 5,344,400 to Kaneko et al. (hereinafter "Kaneko"). It is asserted that Anderson discloses the invention substantially as claimed, but does not disclose the balloon formed from at least two concentric layers of different thermoplastic polymers. However, it is asserted that Kaneko teaches a balloon having the missing limitation, and that it would have been obvious to combine the two reference making claim 43 obvious.

In response, Applicant asserts that Anderson does not disclose the invention substantially as claimed, and therefore the rejection fails. Claim 43 depends upon claim 40 and for the above discussed reasons offered in response to the rejection to claim 40, Anderson does not disclose the invention substantially as claimed, and as such the asserted rejection fails and Applicant respectfully requests that the rejection be withdrawn.

The Examiner also rejects claims 46 and 47 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,500,180 to Anderson et al. (hereinafter "Anderson") in view of U.S. Patent No. 5,167,239 to Cohen et al. (hereinafter "Cohen"). It is asserted that Anderson discloses the invention substantially as claimed, but does not disclose a method of treating a gastrointestinal lesion having the steps as claimed by Applicant. However, it is asserted that

Cohen teaches a device having the missing limitation, and that it would have been obvious to combine the two reference making claims 46 and 47 obvious.

In response, Applicant asserts that Anderson does not disclose the invention substantially as claimed, and therefore the rejection fails. Claims 46 and 47 depend upon claim 40 and for the above discussed reasons offered in response to the rejection to claim 40, Anderson does not disclose the invention substantially as claimed, and as such the asserted rejection fails and Applicant respectfully requests that the rejections be withdrawn.

Furthermore, it is Applicant's contention that such a joining of the aforementioned inventions would still fail to achieve the desired results which the present invention seeks to address. Such a joining would also fail to overcome all of the shortcomings of the prior art which the present invention expressly seeks to overcome. One of the goals that the present invention seeks to overcome is the inherent inefficiency of open surgical repair, over-the-wire passage of a dilator, and several other currently used medical procedures. To this end, the present invention utilizes the technique of balloon dilation. As indicated in Applicant's disclosure, balloon dilation techniques have been shown to exceed other procedures for convenience, effectiveness, and safety. The high compliance, high strength catheter balloon disclosed by Applicant is specifically designed to be used in such balloon dilation procedures. Combining the references in the manner indicated by the Examiner would fail to achieve the inventive and useful process disclosed by Applicant. As such, Applicant respectfully requests that the rejection be withdrawn.

#### *Miscellaneous*

The dependency of claim 47 has been amended to correct an obvious error.

#### *Conclusions*

For the above reasons, the claims are believed to be in condition for allowance. Reconsideration is respectfully requested. Applicant requests that the Examiner call if further

changes or discussions are believed by the Examiner to be necessary to place the case in condition for allowance prior to further action.

Respectfully submitted,  
VIDAS, ARRETT & STEINKRAUS

Date: June 2, 1998

By:

A handwritten signature in black ink, appearing to read 'W. E. Anderson, II', written over a horizontal line.

William E. Anderson, II  
Registration No. 37,766

6109 Blue Circle Drive, Suite 2000  
Minnetonka, MN 55343-9131  
Telephone: (612) 563-3000  
Facsimile: (612) 563-3001  
F:\WPWORK\WEA\6902-AMD.331